Into the Theater of Operations: Hyperbaric Oxygen on the Move

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Abstract

Introduction/rationale: Hyperbaric support for mass casualty injuries resulting from military operations or catastrophic events (i.e., earthquakes, tornadoes, etc.) presently relies upon host country, or at best, local hospital facilities for administration of this therapeutic modality. To get HBO as close to the point of wounding as tactically possible, thus advancing our wartime readiness mission, and addressing the Joint Health Service Support Plan: Vision 2010, easily transportable HBO systems were sought to support deployed aeromedical evacuation operations from remote theaters of operation. The Emergency Evacuation Hyperbaric Stretcher (EEHS) system provides a ready means of quickly initiating treatment at the incident site and transporting the casualty under pressure to a rear–echelon treatment facility, reducing the risks of permanent injury to warfighters suffering from conditions benefited by treatment with hyperbaric oxygen. **Methods and Results:** Pursuant to that goal of a portable chamber system supporting deployed operations a joint service (USAF/USN) collaborative venture was initiated through the Department of Defense funded Foreign Comparative Testing Program. The Navy conducted a battery of environmental, quality assurance and operational performance evaluations of the system ultimately leading to the required American Society of Mechanical Engineer (ASME) certification for human occupancy of a pressure vessel. The Air Force component of this initiative performed aeromedical and human factors evaluations of the system leading to aeromedical approval for flight. Exhaustive evaluation of the EEHS demonstrated a robust, yet lightweight and portable chamber system capable of staged-storage, deployability, rapid treatment initiation, and transport of casualties. Current endeavors are developing instructions for deployment and integrating the EEHS into the operational community. **Summary:** Historically, during contingency operations Hyperbaric Medicine relied upon CONUS, or at best host country, hospital facilities for administration of this important treatment modality. This will no longer be the case. Since we will be able to initiate treatment for the combatant in-theater, we will *preserve the combatant's optimal mission capability* by reducing the magnitude of the injury, and shorten the duration of recovery from battlefield injuries.

Introduction

Hyperbaric Medicine (HBO), in private or civilian practice, has a well established primary role in the clinical treatment and resolution of several chronic disease conditions as well as an adjunctive role in a few acute maladies (5, 7, 15). In military medicine the historic role for HBO has long been, almost exclusively, associated with Decompression Illness (DCI) and the resolution of the physical manifestations evolved nitrogen gas produces on individuals injured by misadventures related to diving or high altitude exposure (11, 12). While this near exclusive association to DCI leveraged the preservation of this modality as a military medical care asset, the landscape of military medicine, as well as advances in science and technology, have focused attention on the greater potential role HBO can posture in military—combat casualty—medicine. The impact this medical subspecialty may have in military readiness could be significant.

Paper presented at the RTO HFM Symposium on "Operational Medical Issues in Hypo- and Hyperbaric Conditions", held in Toronto, Canada, 16-19 October 2000, and published in RTO MP-062.

Much like the reincarnation clinical Hyperbaric Medicine in the United States experienced in the late 20th Century, through hard work of visionaries like Jefferson Davis, Dean Heimbach and others, there is a new investment in the 21st Century future of this modality in critical care medicine—even more important its advancement into the theater of operations. Research endeavors during the past five to eight years indicate HBO can have an influential role in many acute traumatic injury conditions (14, 16) sustained on the battlefield. Very recent investigative efforts are exploring the significant beneficial impact HBO has on injuries sustained from conventional projectile ordinance, and directed energy and biological, mass-effect weapons that are being developed for tomorrow's military operations.

However, to achieve the impact HBO will provide for the injured combatant, a change in the delivery technology must occur. The discipline of Hyperbaric Medicine up to now has limited operational participation due principally to a lack of treatment facilities available for in-theater/field support of combat casualty care and management. The fabrication time, size and cost of contemporary steel pressure vessels made forward deployment impossible. It is critical to the efficacy of hyperbaric oxygen that it be initiated quickly (within 4 - 6 hours) following injury. Therefore, to get HBO as close to the point of wounding as tactically possible, thus advancing our wartime readiness mission and addressing the Joint Health Service Support Plan: Vision 2010, alternate chamber technologies were pursued.

The challenge to the technology was to meet the concept of operations (CONOPS) requirements for low-cost, small cube size, modularity and flexibility needed for deployed aeromedical operations. Moreover, the candidate technology needed to provide a means to evacuate, under pressure if necessary, combatants to and from remote theaters of operation as quickly as possible. Two chamber technologies are currently in testing and/or development. First, for multiplace HBO treatment systems, a concrete/resin composite materials construction that can be quickly (~1month) placed at contingency hospital locations. Second, a modular-panel steel or composite-materials chamber that can be pallet-transported far-forward for deployment or contingency hospital placement and set-up and operating within 24 to 48 hours.

To satisfy the need for a truly portable system that provides safe aeromedical evacuation of theater casualties to a definitive medical hyperbaric treatment facility, a joint a collaborative bi-service effort—United States Air Force (USAF) and United States Navy (USN)—was funded by the Department of Defense, Foreign Comparative Testing (FCT) Program. The focus of this endeavor for both the USAF and USN was to obtain a portable and collapsible hyperbaric system. The principal USN requirement was access for emergency treatment of diving casualties including the capability for a Treatment Table 6A (8). The USN intent is to integrate this system into the Submarine Rescue Diving and Recompression System and the Transportable Recompression Chamber System as well as on-site resolution of DCI at remote dive sites and transfer of diving casualties under pressure. The USAF interest in this technology is to address the near-term need for emergency treatment of altitude induced DCI at sites where host nation or local support is not tenable. However, the USAF has a visionary interest of addressing a long-term need for a deployable system that could be quickly transported to remote, in-theater positions and quickly evacuate injured soldiers to a definitive treatment facility for continued recovery from a myriad of acute traumatic injuries. Then, stabilized patients could be transported safely while pressurized by gurney, ambulance, or aircraft, thus quickly initiating treatment close to the incident site and permitting evacuation, thus reducing the risks of permanent injury to warfighters suffering from conditions benefited by treatment with hyperbaric oxygen.

Procedures:

The FCT evaluation initially identified two candidates systems to be evaluated, one obtained from the United Kingdom, SOS Ltd., and another from Giunio Santi Engineering, Italy. During the program's early evaluation phase it became evident that the latter system would not meet DoD needs, thus the SOS, Ltd. System was the only candidate system advanced to the final testing phase described herein. The emergency evacuation/treatment hyperbaric stretcher (EEHS), a system currently commercially available, is a collapsible vessel constructed of composite materials, approximately 30 inches in diameter, and about seven feet long, when inflated. The pressure vessel proper, excluding hoses and gas supplies, weighs approximately 150 pounds and is self-contained, easily transportable, and capable of withstanding at least 3 Atmospheres Absolute (ATA). Current pressurization procedures employ available air sources (SCUBA cylinders). EEHS is easily set up and pressurized in minutes with minimal training and has a built-in breathing system for oxygen administration with overboard dumping capability during air transport.

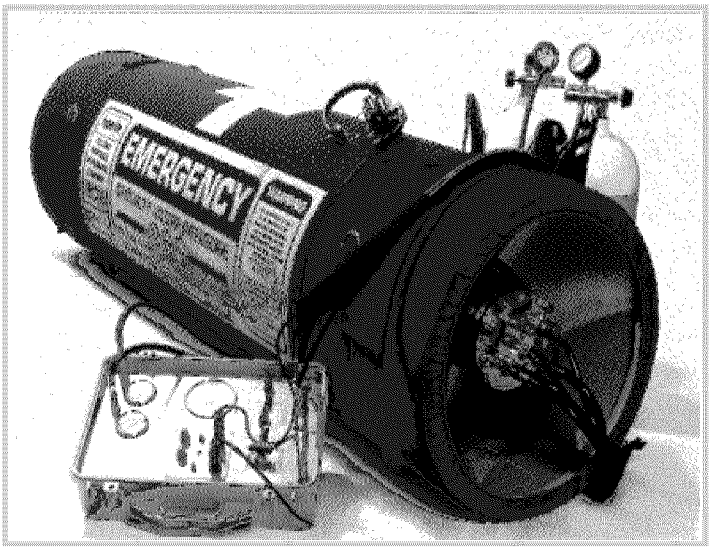

Fig. 1. Emergency Evacuation Hyperbaric Stretcher (EEHS)

Three aspects of the deployable hyperbaric stretcher were evaluated during this collaborative evaluation venture. The USN contribution to the effort was the conduct of a battery of evaluations including component system quality assurance audits, environmental and performance evaluations. The USAF complement to this venture was to demonstrate aeromedical transport compatibility assuring the EEHS and all its components were safe for transport aboard USAF, and to the extent possible, USN and US Army fixed and rotor wing aircraft. Tests by the USAF included a series of system environmental challenges, and several aircraft fit and function evaluations. Both the USN and the USAF performed operational evaluations to assure the EEHS would be usable in a deployed operational environment. The objective of these evaluations was to provide DoD with a hyperbaric stretcher system that meets the needs of the forward deployed units, as well as provide access to hyperbaric oxygen for victims of natural or terrorist caused mass casualties.

In the United States, Canada, 58 recognizing countries and for this activity the DoD, vessels wherein a human is exposed to increased ambient pressure must be manufactured and perform in accordance with a standard set by the American Society of Mechanical Engineers (ASME) (3, 13). Furthermore, to ensure that the designer and fabricator of a medical hyperbaric vessel employ a minimum safety standard for these vessels the Main Committee for Pressure Vessels for Human Occupancy (PVHO) developed rules (PVHO-1) for guiding construction (10). While the U.S. Food and Drug Administration (FDA) regulates hyperbaric vessels as Class II medical devices, any vessel meeting the PVHO-1 specifications will have an easier time achieving FDA approval. The standards cited above apply generally to metallic vessels. Recent technological advances with flexible, nonmetallic vessels—the focus of this activity—led to application of a Case exception to the rules defined for metallic chambers. So, it is to the PVHO Code Case 6 standard that the USN challenged the EEHS to meet assuring a well-constructed and safe operating system for deployable use.

Tasks performed by the USN in pursuit of Code Case approval of this system included, but were not limited to, the following tests:

1. Cyclic hydrostatic pressure test simulating repetitive usage. This evaluation assessing long term performance and endurance consisted of more than 4000 cyclic pressurizations from baseline to the design pressure of slightly more than 3 ATA.
2. Extreme temperature storage and inflation to evaluate the system's ability to tolerate environmental stress of cold (-40°C) and heat (+60°C). Following exposure to the respective thermal stress, the system was either warmed to –18°C from -40°C, or cooled to +49°C from +60°C, then inflated to operating pressure and monitored for performance.
3. Hydrostatically pressure tested to at least five times the rated pressure of the vessel to ensure a proper safety factor is present.
4. Solar radiation to evaluate performance following prolonged sunlight exposure (300 hrs; bandwidth 0.28 to 3.0 μm and >11 W/m2).
5. Salt fog to evaluate tolerance for exposure to high salt environment (6% sodium chloride solution with specific gravity of approximately 1.04).
6. Vibration (11-2000 Hz) to test susceptibility to component breakdown under random and sinusoidal vibration (30 min x, y and z axis).
7. Off axis drop test to evaluate integrity against damage from accidental drop (45° from 3 feet elevation).

Fig. 2. Containerized EEHS and components

All the aforementioned tasks included a thorough inspection of the system at least prior to and following each challenge. Often, intermediate inspections were conducted during the challenge to assess pressure and integrity of the system to the challenge. Finally, to complete the assessment, and in compliance with PVHO-1 requirements, a free and unbiased inspection of the material quality assessment plan, manufacturing operations and quality control assurance was performed.

Supplementary to the materials and components tests, pursuant to the ASME-PVHO requirements, the Naval Experimental Diving Unit (NEDU) performed several functional and operational evaluations to assess the suitability of the system for deployment. The complete description of the tests and results are chronicled in a report of that activity (9). Briefly, the operational tests were directed at a functional assessment including: a) ease of set-up and transfer of system into a multiplace chamber, b) transport evacuation from a remote shore based location to a treatment facility, c) transport using a small (36-foot length) boat to a treatment facility, and d) transfer simulation from a primary treatment chamber into EEHS, then transfer to a remote treatment facility. In addition to these unmanned evaluations several manned exposures were performed. The focus of these manned evaluations was to identify any human factor issues needing special training provisions or component modifications prior to deployment.

The USAF contribution to this collaborative venture was the appraisal of the EEHS for air transportability certification and approval for use in-flight, thus providing access to aeromedical evacuation. Similar in consideration with regard to safety aspects of materials and fabrication defined by ASME-PVH, safety considerations are defined for air transport of medical instruments and devices. These requirements are defined in Air Force Instructions (AFI) concerning General Flight Rules (1) and Aeromedical Evacuation Equipment Standards (2). The Air Force Research Protective Systems Branch was charged with the responsibility for evaluating and determining acceptability of medical equipment to be used aboard fixed and rotor wing aircraft.

The matrix of tests conducted, some of which were similar to those performed by the USN and repeated as a part of this evaluation (i.e., vibration, hot and cold storage and system performance), to attain the air transportability certificate for the EEHS included:

1. Baseline system performance to familiarize the evaluation team with the system and to note any potential safety issues related to the aeromedical evacuation environment.
2. Electromagnetic interference evaluation of electrical components of the system to assess potential interactions generated by the system influencing the aircraft, or, conversely aircraft produced electromagnetic forces affecting operation of the system.
3. Altitude exposures at a flight level of 15, 000 feet to assure monitoring components and systems function are reliable in this hypobaric environment.
4. Rapid decompression of EEHS whilst in operation to approximate stresses imposed during an emergency or accidental decompression of the aircraft during transport of a patient. This test was operated three separate times from a base of 8,000 feet decompressed to 45,000 feet at time intervals of 60s, 7s and 1s, respectfully.
5. Vibration curves representing lifetime exposures to three different classes of aircraft signatures were performed. Random frequency profiles (20 to 2000 Hz) and sinusoidal-on-random frequency curves (10 to 500 Hz) were employed for each of the three major axes of the system. All components were active during this test and performance assessments were carried out at 15-min intervals for the 60-min test. This evaluation was conducted to assure component in-flight function and reliability, and to identify any patient safety and welfare issues related to in-flight transport.

Finally, and an equally important adjunct to the static aeromedical evaluation tests mentioned above, was the airborne performance evaluations and analysis of the EEHS for placement, security, fit and function for several airframes. Principal among these evaluations included detailing methods for in-flight security of the system for safe travel and for emergency conditions including air turbulence and in-flight emergencies. Also, another important assessment of this task was to exercise the patient/operator communications issues in the noisy aeromedical transport environment. The comprehensive results of this evaluation are contained in a Technical Report composed by the executing agency (4).

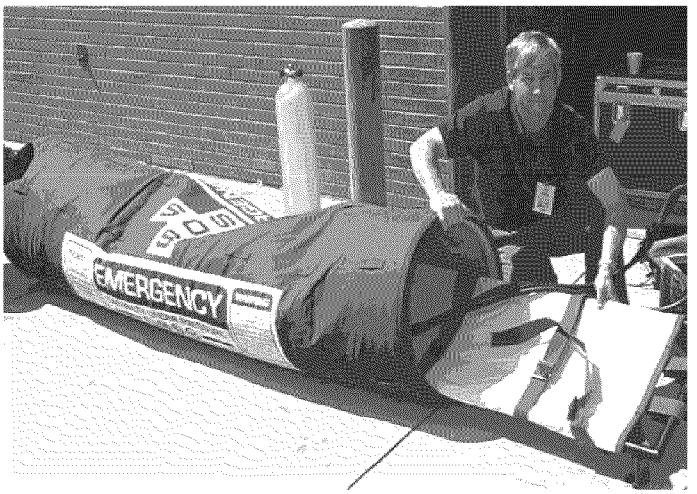

Fig. 3. EEHS Extended Ready for Patient Ingress

Discussion:

The USAF Aeromedical Evacuation has the DoD responsible mission to provide tactical and strategic aeromedical evacuation of casualties for all US military services. Currently, the USAF has no available system to address the need for safe aeromedical evacuation of theater casualties suffering from decompression illness, arterial gas embolism, carbon monoxide poisoning or gas gangrene for hyperbaric treatment. Furthermore, the USN has an identified need for a portable system to evacuate casualties from submerged disabled submarines (DISSUB) and remote dive site transfer of diving casualties under pressure. These needs led to a joint collaborative, non-developmental, evaluation of a portable hyperbaric system. The USN conducted fabrication and materials certification tests, and the USAF was responsible for achieving aeromedical transportability certification.

The combined USN ASME-PVHO and USAF air transportability certification evaluations previously described provided a rigorous baseline and detailed assessment of the capability of the candidate hyperbaric

evacuation/treatment system. The EEHS performed well in all aspects, manned and unmanned, of the testing program. Comprehensive discussion of the results of the USN and the USAF test programs are available for review. Briefly, the system met or exceeded the major benchmark requirements for ASME-PVHO-1 CODE and Aeromedical transport certification and approval. There were some minor-to-moderate adjustments made in sub-components of the system, but in summary, the system performed to required mission objectives. Notwithstanding the thorough nature of the performed tests, there are substantial implementation and procedural issues remaining to be addressed. Some of these issues are considered in a report by Latson and Flynn () concerning use of the EEHS in submarine escape and rescue. With regard to USAF aeromedical evacuation mission objectives, a draft report is being prepared.

Now that a viable transportable hyperbaric stretcher system is available for deployment, the next level of integration into the operational community is provision of technical and operational consultation to the deployed units. For DISSUB and remote site support, the USN relies principally upon master divers for operation and performance of the treatment tables for the injured individuals. The USAF, given the therapeutic mission requirements for the EEHS system, requires flight surgeon (trained in hyperbaric medicine) oversight for operation and transport accompaniment of the injured individual. Toward that objective a Concept of Operations for the Hyperbaric Care Air Transport (HCAT) Team has been drafted (6) as a Unit Type Code and is actively seeking sanction. The HCAT team would be composed of one Hyperbaric trained physician, one hyperbaric critical care nurse, and one aerospace physiology technician. Expertise of this team would carry the EEHS system (HCAT-A) when deployed. In general, the HCAT team would assist the aeromedical evacuation mission providing a limited, rapidly deployable resource to oversee hyperbaric care and offer expert counsel for the management of injured patients in transit to the definitive care target destination. Presently three HCAT Teams are being recommended.

Summary:

Historically, during contingency operations Hyperbaric Medicine relied upon Continental United States (CONUS) or at best host agency hospital facilities for administration of this important modality. This will no longer be the case. Since we are able to initiate treatment for the combatant, in-theater, we will *preserve the combatant's optimal mission capability* by reducing the magnitude of the injury, and shortening the duration of recovery from many battlefield injuries. Moreover, HBO will become an important player in DoD humanitarian efforts in support of casualties sustained by individuals from natural disaster and terrorist activities.

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